

AMENDED IN ASSEMBLY MARCH 31, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2436**

**Introduced by Assembly Member Bates**

February 19, 2004

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An act to amend ~~Section 1206.5~~ *Sections 1206.5, 1244, and 1246.5* of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2436, as amended, Bates. Clinical laboratory testing.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Services *and makes a violation of these provisions a misdemeanor*. Under existing law, only designated health care personnel are authorized to perform, under specified conditions, clinical laboratory tests or examinations that are classified as waived, moderate complexity, or high complexity under federal law. *Existing law also specifies conditions for the operation of a nondiagnostic general health assessment program.*

This bill would authorize a person performing a nondiagnostic general health assessment to also perform, under specified conditions, a clinical laboratory test or examination that is classified as “waived.” *The bill would also specify additional conditions for the operation of a nondiagnostic general health assessment program. Because a violation of these additional requirements would be a crime, the bill would impose a state-mandated local program.*

*The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.*

*Statutory provisions establish procedures for making that reimbursement.*

*This bill would provide that no reimbursement is required by this act for a specified reason.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ yes.  
State-mandated local program: ~~no~~ yes.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 1206.5 of the Business and Professions
- 2 Code is amended to read:
- 3 1206.5. (a) Notwithstanding subdivision (b) of Section 1206
- 4 and except as otherwise provided in Section 1241, no person shall
- 5 perform a clinical laboratory test or examination classified as
- 6 waived under CLIA unless the clinical laboratory test or
- 7 examination is performed under the overall operation and
- 8 administration of the laboratory director, as described in Section
- 9 1209, including, but not limited to, documentation by the
- 10 laboratory director of the adequacy of the qualifications and
- 11 competency of the personnel, and the test is performed by any of
- 12 the following persons:
- 13 (1) A licensed physician and surgeon holding a M.D. or D.O.
- 14 degree.
- 15 (2) A licensed podiatrist or a licensed dentist if the results of the
- 16 tests can be lawfully utilized within his or her practice.
- 17 (3) A person licensed under this chapter to engage in clinical
- 18 laboratory practice or to direct a clinical laboratory.
- 19 (4) A person authorized to perform tests pursuant to a
- 20 certificate issued under Article 5 (commencing with Section
- 21 101150) of Chapter 2 of Part 3 of Division 101 of the Health and
- 22 Safety Code.
- 23 (5) A licensed physician assistant if authorized by a supervising
- 24 physician and surgeon in accordance with Section 3502 or Section
- 25 3535.
- 26 (6) A person licensed under Chapter 6 (commencing with
- 27 Section 2700).
- 28 (7) A person licensed under Chapter 6.5 (commencing with
- 29 Section 2840).
- 30 (8) A perfusionist if authorized by and performed in
- 31 compliance with Section 2590.



1 (9) A respiratory care practitioner if authorized by and  
2 performed in compliance with Chapter 8.3 (commencing with  
3 Section 3700).

4 (10) A medical assistant, as defined in Section 2069, if the  
5 waived test is performed pursuant to a specific authorization  
6 meeting the requirements of Section 2069.

7 (11) A pharmacist, as defined in Section 4036, if ordering drug  
8 therapy-related laboratory tests in compliance with clause (ii) of  
9 subparagraph (A) of paragraph (5) of, or subparagraph (B) of  
10 paragraph (4) of, subdivision (a) of Section 4052, or if performing  
11 skin puncture in the course of performing routine patient  
12 assessment procedures in compliance with Section 4052.1.

13 (12) Other health care personnel providing direct patient care.

14 (13) Any other person performing nondiagnostic testing  
15 pursuant to Section 1244.

16 (b) Notwithstanding subdivision (b) of Section 1206, no person  
17 shall perform clinical laboratory tests or examinations classified  
18 as of moderate complexity under CLIA unless the clinical  
19 laboratory test or examination is performed under the overall  
20 operation and administration of the laboratory director, as  
21 described in Section 1209, including, but not limited to,  
22 documentation by the laboratory director of the adequacy of the  
23 qualifications and competency of the personnel, and the test is  
24 performed by any of the following persons:

25 (1) A licensed physician and surgeon holding a M.D. or D.O.  
26 degree.

27 (2) A licensed podiatrist or a licensed dentist if the results of the  
28 tests can be lawfully utilized within his or her practice.

29 (3) A person licensed under this chapter to engage in clinical  
30 laboratory practice or to direct a clinical laboratory.

31 (4) A person authorized to perform tests pursuant to a  
32 certificate issued under Article 5 (commencing with Section  
33 101150) of Chapter 2 of Part 3 of Division 101 of the Health and  
34 Safety Code.

35 (5) A licensed physician assistant if authorized by a supervising  
36 physician and surgeon in accordance with Section 3502 or Section  
37 3535.

38 (6) A person licensed under Chapter 6 (commencing with  
39 Section 2700).

1 (7) A perfusionist if authorized by and performed in  
2 compliance with Section 2590.

3 (8) A respiratory care practitioner if authorized by and  
4 performed in compliance with Chapter 8.3 (commencing with  
5 Section 3700).

6 (9) A person performing nuclear medicine technology if  
7 authorized by and performed in compliance with Article 6  
8 (commencing with Section 107150) of Chapter 4 of Part 1 of  
9 Division 104 of the Health and Safety Code.

10 (10) Any person if performing blood gas analysis in  
11 compliance with Section 1245.

12 (11) (A) A person certified or licensed as an “Emergency  
13 Medical Technician II” or paramedic pursuant to Division 2.5  
14 (commencing with Section 1797) of the Health and Safety Code  
15 while providing prehospital medical care, a person licensed as a  
16 psychiatric technician under Chapter 10 (commencing with  
17 Section 4500) of Division 2, as a vocational nurse pursuant to  
18 Chapter 6.5 (commencing with Section 2840), or as a midwife  
19 licensed pursuant to Article 24 (commencing with Section 2505)  
20 of Chapter 5, or certified by the department pursuant to Division  
21 5 (commencing with Section 70001) of Title 22 of the California  
22 Code of Regulations as a nurse assistant or a home health aide, who  
23 provides direct patient care, if the person is performing the test as  
24 an adjunct to the provision of direct patient care by the person, is  
25 utilizing a point-of-care laboratory testing device at a site for  
26 which a laboratory license or registration has been issued, meets  
27 the minimum clinical laboratory education, training, and  
28 experience requirements set forth in regulations adopted by the  
29 department, and has demonstrated to the satisfaction of the  
30 laboratory director that he or she is competent in the operation of  
31 the point-of-care laboratory testing device for each analyte to be  
32 reported.

33 (B) Prior to being authorized by the laboratory director to  
34 perform laboratory tests or examinations, testing personnel  
35 identified in subparagraph (A) shall participate in a preceptor  
36 program until they are able to perform the clinical laboratory tests  
37 or examinations authorized in this section with results that are  
38 deemed accurate and skills that are deemed competent by the  
39 preceptor. For the purposes of this section, a “preceptor program”  
40 means an organized system that meets regulatory requirements in

1 which a preceptor provides and documents personal observation  
2 and critical evaluation, including review of accuracy, reliability,  
3 and validity, of laboratory testing performed.

4 (12) Any other person within a physician office laboratory if  
5 the test is performed under the supervision of the patient's  
6 physician and surgeon or podiatrist who shall be accessible to the  
7 laboratory to provide onsite, telephone, or electronic consultation  
8 as needed, and shall: (A) ensure that the person is performing test  
9 methods as required for accurate and reliable tests; and (B) have  
10 personal knowledge of the results of the clinical laboratory testing  
11 or examination performed by that person before the test results are  
12 reported from the laboratory.

13 (13) A pharmacist, if ordering drug therapy-related laboratory  
14 tests in compliance with clause (ii) of subparagraph (A) of  
15 paragraph (5) of, or subparagraph (B) of paragraph (4) of,  
16 subdivision (a) of Section 4052.

17 (c) Notwithstanding subdivision (b) of Section 1206, no person  
18 shall perform clinical laboratory tests or examinations classified  
19 as of high complexity under CLIA unless the clinical laboratory  
20 test or examination is performed under the overall operation and  
21 administration of the laboratory director, as described in Section  
22 1209, including, but not limited to, documentation by the  
23 laboratory director of the adequacy of the qualifications and  
24 competency of the personnel, and the test is performed by any of  
25 the following persons:

26 (1) A licensed physician and surgeon holding a M.D. or D.O.  
27 degree.

28 (2) A licensed podiatrist or a licensed dentist if the results of the  
29 tests can be lawfully utilized within his or her practice.

30 (3) A person licensed under this chapter to engage in clinical  
31 laboratory practice or to direct a clinical laboratory if the test or  
32 examination is within a specialty or subspecialty authorized by the  
33 person's licensure.

34 (4) A person authorized to perform tests pursuant to a  
35 certificate issued under Article 5 (commencing with Section  
36 101150) of Chapter 2 of Part 3 of Division 101 of the Health and  
37 Safety Code if the test or examination is within a specialty or  
38 subspecialty authorized by the person's certification.

1 (5) A licensed physician assistant if authorized by a supervising  
2 physician and surgeon in accordance with Section 3502 or Section  
3 3535.

4 (6) A perfusionist if authorized by and performed in  
5 compliance with Section 2590.

6 (7) A respiratory care practitioner if authorized by and  
7 performed in compliance with Chapter 8.3 (commencing with  
8 Section 3700).

9 (8) A person performing nuclear medicine technology if  
10 authorized by and performed in compliance with Article 6  
11 (commencing with Section 107150) of Chapter 4 of Part 1 of  
12 Division 104 of the Health and Safety Code.

13 (9) Any person if performing blood gas analysis in compliance  
14 with Section 1245.

15 (10) Any other person within a physician office laboratory if  
16 the test is performed under the onsite supervision of the patient's  
17 physician and surgeon or podiatrist who shall: (A) ensure that the  
18 person is performing test methods as required for accurate and  
19 reliable tests; and (B) have personal knowledge of the results of  
20 clinical laboratory testing or examination performed by that  
21 person before the test results are reported from the laboratory.

22 (d) Clinical laboratory examinations classified as  
23 provider-performed microscopy under CLIA may be personally  
24 performed using a brightfield or phase/contrast microscope by one  
25 of the following practitioners:

26 (1) A licensed physician and surgeon using the microscope  
27 during the patient's visit on a specimen obtained from his or her  
28 own patient or from a patient of a group medical practice of which  
29 the physician is a member or employee.

30 (2) A nurse midwife holding a certificate as specified by  
31 Section 2746.5, a licensed nurse practitioner as specified in  
32 Section 2835.5, or a licensed physician assistant acting under the  
33 supervision of a physician pursuant to Section 3502 using the  
34 microscope during the patient's visit on a specimen obtained from  
35 his or her own patient or from the patient of a clinic, group medical  
36 practice, or other health care provider of which the certified nurse  
37 midwife, licensed nurse practitioner, or licensed physician  
38 assistant is an employee.

39 (3) A licensed dentist using the microscope during the patient's  
40 visit on a specimen obtained from his or her own patient or from

1 a patient of a group dental practice of which the dentist is a member  
2 or an employee.

3 *SEC. 2. Section 1244 of the Business and Professions Code is*  
4 *amended to read:*

5 1244. (a) Nothing in this chapter shall restrict, limit, or  
6 prevent a program of nondiagnostic general health assessment  
7 provided that:

8 (1) The program meets the requirements of Section 1265 and  
9 complies with the requirements of CLIA *for waived testing*.

10 (2) The purpose of the program is to *screen asymptomatic*  
11 *individuals for chronic health disorders and to refer individuals to*  
12 *licensed sources of care as indicated.*

13 (3) The program utilizes only those devices that comply with  
14 all of the following:

15 (A) Meet all applicable state and federal performance  
16 standards pursuant to Section 111245 of the Health and Safety  
17 Code.

18 (B) Are not adulterated as specified in Article 2 (commencing  
19 with Section 111250) of Chapter 6 of Part 5 of Division 104 of the  
20 Health and Safety Code.

21 (C) Are not misbranded as specified in Article 3 (commencing  
22 with Section 111330) of Chapter 6 of Part 5 of Division 104 of the  
23 Health and Safety Code.

24 (D) Are not new devices unless they meet the requirements of  
25 Section 111550 of the Health and Safety Code.

26 ~~(4)~~

27 (E) *Are approved as waived tests and are used according to the*  
28 *manufacturer's instructions.*

29 (4) *Blood collection is performed by skin puncture only.*

30 (5) *Testing of a urine specimen is performed by the dip stick*  
31 *method only.*

32 (6) *Testing is performed on site and reported directly to the*  
33 *person requesting the test.*

34 (7) The program maintains a supervisory committee consisting  
35 of, at a minimum, a licensed physician and surgeon and a *clinical*  
36 *laboratory technologist scientist* licensed pursuant to this chapter.

37 ~~(5)~~

38 (8) The supervisory committee for the program adopts written  
39 protocols that shall be followed in the program and that shall  
40 contain all of the following:



1 (A) Provision of written information to individuals to be  
2 assessed that shall include, but not be limited to, the following:

3 (i) The potential risks and benefits of assessment procedures to  
4 be performed in the program.

5 (ii) The limitations, including the nondiagnostic nature, of  
6 assessment examinations of biological specimens performed in  
7 the program.

8 (iii) Information regarding the risk factors or markers targeted  
9 by the program.

10 (iv) The need for followup with licensed sources of care for  
11 confirmation, diagnosis, and treatment as appropriate.

12 (B) Proper use of each device utilized in the program including  
13 the operation of analyzers, maintenance of equipment and  
14 supplies, and performance of quality control procedures including  
15 the determination of both accuracy and reproducibility of  
16 measurements in accordance with instructions provided by the  
17 manufacturer of the assessment device used.

18 (C) Proper procedures to be employed when ~~drawing~~  
19 *collecting* blood, if blood specimens are to be obtained.

20 (D) Proper procedures to be employed in handling and  
21 disposing of all biological specimens to be obtained and material  
22 contaminated by those biological specimens. *These procedures*  
23 *shall comply with all county and city ordinances for medical waste*  
24 *management and blood-borne pathogen control that apply to the*  
25 *location where the program operates.*

26 (E) Proper procedures to be employed in response to fainting,  
27 excessive bleeding, or other medical emergencies.

28 (F) *Documentation that the testing personnel are following the*  
29 *instructions of the instrument's manufacturer, are trained in the*  
30 *performance of the test, and are competent to perform the testing*  
31 *without supervision.*

32 (G) Reporting of assessment results to the individual being  
33 assessed.

34 ~~(G)~~

35 (H) Referral and followup to licensed sources of care as  
36 indicated.

37 The written protocols adopted by the supervisory committee  
38 shall be maintained for at least one year following completion of  
39 the assessment program during which period they shall be subject



1 to review by department personnel and the local health officer or  
2 his or her designee, including the public health laboratory director.

3 (b) If skin puncture to obtain a blood specimen is to be  
4 performed in a program of nondiagnostic general health  
5 assessment, the individual performing the skin puncture shall be  
6 either:

7 ~~(1) Authorized~~ *authorized* to perform skin puncture under this  
8 chapter.

9 ~~(2) Any person who possesses a statement signed by a licensed~~  
10 ~~physician and surgeon that attests that the named person has~~  
11 ~~received adequate training in the proper procedure to be employed~~  
12 ~~in skin puncture.~~

13 (c) A program of nondiagnostic general health assessment that  
14 fails to meet the requirements set forth in subdivisions (a) and (b)  
15 shall not operate.

16 (d) For purposes of this section, “skin puncture” means the  
17 collection of a blood specimen by the finger prick method only and  
18 does not include venipuncture, arterial puncture, or any other  
19 procedure for obtaining a blood specimen.

20 (e) Nothing in this chapter shall be interpreted as prohibiting a  
21 licensed clinical laboratory from operating a program of  
22 nondiagnostic general health assessment provided that the clinical  
23 laboratory complies with the requirements of this section.

24 *(f) A program for a health fair providing diagnostic or*  
25 *screening tests is not a nondiagnostic general health assessment*  
26 *program if all of the requirements of this chapter are met, and the*  
27 *laboratory performing the testing is licensed under paragraph (1)*  
28 *of subdivision (a) of Section 1265. For a test that is not authorized*  
29 *for self-ordering pursuant to Section 1246.5 or for a nondiagnostic*  
30 *general health assessment pursuant to this section, the licensed*  
31 *clinical laboratory participating in the health fair shall arrange*  
32 *for the test to be ordered by a person licensed under this division*  
33 *who is authorized to order the test. The results of a test performed*  
34 *at a health fair shall be provided to the test subject along with an*  
35 *explanation of the results.*

36 SEC. 3. Section 1246.5 of the Business and Professions Code  
37 is amended to read:

38 1246.5. Notwithstanding any other provision of law, any  
39 person may request, and any licensed clinical laboratory or public  
40 health laboratory may perform, the laboratory tests specified in

1 this section. A registered clinical laboratory may perform the  
2 laboratory tests specified in this section if the test is subject to a  
3 certificate of waiver under CLIA and the laboratory has registered  
4 with the department under paragraph (2) of subdivision (a) of  
5 Section 1265. *A program for nondiagnostic general health*  
6 *assessment that includes a laboratory test specified in this section*  
7 *shall comply with the provisions of Section 1244.* The results from  
8 any test may be provided directly to the person requesting the test  
9 if the test is on or for his or her own body. These test results shall  
10 be provided in a manner that presents clear information and that  
11 identifies results indicating the need for referral to a physician and  
12 surgeon.

13 The tests that may be conducted pursuant to this section are:  
14 pregnancy, glucose level, cholesterol, occult blood, and any other  
15 test for which there is a test for a particular analyte approved by  
16 the federal Food and Drug Administration for sale to the public  
17 without a prescription in the form of an over-the-counter test kit.

18 *SEC. 4. No reimbursement is required by this act pursuant to*  
19 *Section 6 of Article XIII B of the California Constitution because*  
20 *the only costs that may be incurred by a local agency or school*  
21 *district will be incurred because this act creates a new crime or*  
22 *infraction, eliminates a crime or infraction, or changes the penalty*  
23 *for a crime or infraction, within the meaning of Section 17556 of*  
24 *the Government Code, or changes the definition of a crime within*  
25 *the meaning of Section 6 of Article XIII B of the California*  
26 *Constitution.*

